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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/659,291
Filing Date: September 11, 2003
Appellant(s): MARKES, ROBERT

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Mr. David Klein
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 3/22/10 appealing from the Office action mailed 10/23/09.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

Claims 1, 5-10 and 12-20.

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

**WITHDRAWN REJECTIONS**

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. In an effort to reduce the issues

for the BPAI to consider, the Office has vacated the rejections over Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492) and Moerman et al. (USP 6,706,159) which are duplicative. The Office believes the remaining primary reference Steine et al. is the best reference.

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| 2004/0219523 | Stanton et al. | 11-2004 |
| 2004/0096959 | Stiene et al. | 05-2004 |
| 5,186,897 | Eason et al. | 02-1993 |
| 4,941,473 | Tenerz et al. | 07-1990 |

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5-10 and 12-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stiene et al. (2004/0096959) in view of Eason et al (USP 5,186,897) alone or further in view of Tenerz et al. (USP 4,941,473).

Stiene et al. teach a glucose sensor comprising a microneedle (4), electro-osmotic pump (10), microchannel (8) and detector (11). Paragraph[025] teach the device is **"optochemical-i.e. either fluorescent or luminescent"** which has been read on the claimed *"optical sensor"*. Paragraph [026] teaches the use of various enzymes to facilitate glucose detection and have been read on the claimed reagent. Paragraph[027] teaches the " ... analyte sensing means operates in conjunction with a test meter to give the measurement … such arrangements are consistent with the test device being disposable since the light sensitive means, electronic circuitry , etc., can be place in a non-disposable test meter. " The Office has read the taught "analyte sensing means" and the "test meter" on the claimed "first housing" and "second housings" respectively. The Office has further read the taught "light sensitive means, electronic circuitry" on the claimed processor and photodiode that converts light emissions to a measurable current that is correlated to the glucose concentration.

Paragraph [0107] teaches a waste reservoir in figure 17(b). Paragraph [081] teaches the device is “disposable”. Paragraph [044] teaches the pumping can be either mechanical or electro-osmotic. Paragraph [062] teaches display means coupled directly to the device or could receive the data from the device by telemetry which has been read on the claimed optical/data link between the display means (e.g. the processor) and the device in contact with the skin. Paragraphs[064-067] teach the sensor connected to the appropriate processor for controlling an insulin pump in response to the glucose concentrations. Alternatively, the Office has read the claimed "first housing" on the device in contact with the skin and the "second housing" on the processor for controlling the insulin pump. Paragraph [0118] teaches wireless technology.

Steine et al. teach an optical sensor but is silent to use of an “optical waveguide.”

Eason et al. teach a multi-analyte test device. Eason et al. teach in column 2 lines 15-22 optical waveguides are advantageous because they “… reduce the need for operator attention and avoids the need for physical separation or washing steps in the assay.”

Simple substitution of one known element for another to obtain predictable results is held to be obvious. It would have been within the skill of the art to modify Steine et al. in view of Eason et al. and substitute an optical waveguide to contact the sample to gain the above advantages of less operator attention and the need to separate and wash the sample.

Steine et al. in view of Eason et al. are silent to the connection of a first waveguide in the first housing connected to a second waveguide in the second housing.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. It is well know in the art to connect a waveguide with the processor by a waveguide. Further, it is well known when testing biological sample, it is desirable to make the portion of the test device in contact with the sample disposable to minimize the opportunity of contamination to the equipment or user. The selection of the connection of a waveguide to the processor is a result effective variable having the well known and expected results of providing a signal representative of the sample to the processor.

It would have been within the skill of the art to further modify Stiene et al. (2004/0096959) in view of Eason et al. and use an optical waveguide having a first portion that is in contact with the biological sample connected to a second portion that is in contact with the processor as optimization of a result effective variable and to gain the above advantages.

Tenerz et al. teach in column 2 lines 10-55 it is convention to attach or weld a first optical fiber that is in contact with the sample to a second optical fiber that is associated with the detector. This is advantageous so that a more flexible fiber can be used to contact the sample and a stiffer fiber in contact with the detector. The original specification of this application teaches on page 4 lines 2-3 that optical fibers are wave guides. Office has read the taught optical fibers on the claimed waveguides.

It would have been with in the skill of the art to modify Stiene et al. (2004/0096959) in view of Eason et al. and further in view of Tenerz et al. and attach

two different segments of fiber to gain the above advantages of a more flexible fiber to contact the sample and a stiffer fiber in contact with the detector.

With respect to claim 18, the modified apparatus of Stiene et al. are silent to the type of light, either coherent or non-coherent, that is used for the analysis. However, it is inherent the optical device taught by Stiene et al. would use one of the two claimed types of light (e.g. Steine et al. would either use coherent or non-coherent light).

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The selection of the type of light best suited to resolve the particular analyte/reagent combination is a result effective variable. The selection of either coherent or non-coherent light is a result effective variable having the well known and expected results of providing the optimal conditions to best resolve the particular analyte/reagent combination.

It would have been within the skill of the art to further modify the modified apparatus of Stiene et al. (2004/0096959) and use either coherent or non-coherent light as optimization of a result effective variable and to gain the above advantages.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable Stiene et al. (2004/0096959) in view of Eason et al (USP 5,186,897) alone or further in view of Tenerz et al. (USP 4,941,473) as applied to claims 1, 5-10 and 12-19 above, and further in view of Stanton et al (US 2004/0219523).

Stiene et al. (2004/0096959) in view of Eason et al (USP 5,186,897) alone or further in view of Tenerz et al. (USP 4,941,473) are silent to the use of a "surface Plasmon resonance sensor."

Stanton et al. teach in paragraph [0255] a "surface Plasmon resonance sensor" (referenced hereafter as "SPR") in combination with a waveguide to gain the advantages of real time analysis of biological sample. Paragraph[0351] teaches it is known to incorporate a biosensor into a fiber optic waveguide. Additionally, paragraph[0138] teaches real time data is generated by SPR sensor systems as shown in figures 67C and 67D. Paragraph[0767] teach the SPR provides very sensitive analysis of binding/unbinding of analytes. Paragraph[0768] teaches the "SPReeta" is an integrated package comprising a LED, SPR and a diode array. The light from the LED that impinges the SPR surface is detected by the diode array.

It would have been within the skill of the art to use a known technique to improve a similar device in the same way. Stanton et al. teaches SPR is known and used in combination with a waveguide for analysis of analytes in biological fluids. Stanton et al. also teach the SPR is advantageous because it provides sensitive, real time analysis of the analytes.

It would have been within the skill of the art to further modify Stiene et al. (2004/0096959) in view of Eason et al (USP 5,186,897) alone or further in view of Tenerz et al. (USP 4,941,473) as applied to claims 1, 5-10 and 12-19 above, and further in view of Stanton et al (US 2004/0219523) and use a SPR sensor to gain the above advantages.

**(10) Response to Argument**

In an effort to reduce the issues for the BPAI to consider, the Office has vacated the rejections over Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), and Moerman et al. (USP 6,706,159). The primary reference is now Stiene et al.

Appellant traverses the combination of Stiene et al. with Eason et al. on the basis Eason et al. only teaches the use of an optical waveguide and does not teach the claimed connection of a first and second waveguides. The Office agrees with Appellant that Eason et al. has only been applied to teach that optical waveguides are advantageous. The Office has applied Tenerz et al. to teach the connection of two waveguides. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Office maintains Stiene et al. in view of Eason et al. has been properly applied.

On page 10 paragraph 4, Appellant further traverses the combination of Stiene et al. in view of Eason et al. stating the combination fails to teach the claimed combination of a microprocessor and a photodiode. Appellant states Stiene et al. does not teach the claimed “optical sensor”. The Office does not agree. Stiene et al. teach in paragraph[027] the “ ... analyte sensing means operates in conjunction with a test meter to give the measurement … such arrangements are consistent with the test device being disposable since the light sensitive means, electronic circuitry , etc., can be place

in a non-disposable test meter. " The Office has read the taught "light sensitive means, electronic circuitry" on the claimed photodiode and processor respectively. The Office maintains the combination of Stiene et al. in view of Eason et al. is proper.

On page 11 of the Brief, Appellant state the SPR sensor system taught Stanton et al. in " paragraph[0138] has nothing to do with the optical sensor comprising a SPR sensor as claimed in claim 20." The Office does not agree. Stanton et al. teach in paragraph[0768] the "SPReeta" is an integrated package comprising a LED, SPR and a diode array. The light from the LED that impinges the SPR surface is detected by the diode array. The Office maintains Stanton et al. teach an optical sensor comprising a SPR and the rejections of record are proper.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,
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/Jill Warden/
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